



## **TRIAL STUDY PARTICIPATION**

### **I. PURPOSE**

To define the requirements for Emergency Medical Services (EMS) providers or hospitals to participate in California EMS Authority (EMSA) approved trial studies in the Inland Counties Emergency Medical Agency (ICEMA) region.

### **II. ELIGIBILITY**

Participating EMS providers and hospitals must:

- Designate an EMS Coordinator or Continuous Quality Improvement (CQI) Coordinator respectively.
- EMS providers must be current participants on the ICEMA Data System and complete all the required fields on the electronic patient care record (ePCR) for the duration of the study.
- EMS or CQI Coordinators must review all enrolled cases within 24 hours and report any adverse effects to ICEMA immediately.
- All EMS field personnel and hospital staff participating in the trial study must successfully complete all educational offerings or competencies for the duration of the study.
- Hospitals must compile and submit all relevant data elements as requested by ICEMA.
- Due to the nature of these trial studies and safety concerns, the EMS or CQI Coordinators must participate in all Trial Study CQI Review meetings and incident reviews of enrolled trial study cases. Additionally, all personnel directly involved in these trial studies may be required to attend and participate in Trial Study CQI Review meetings.
- EMS providers and hospitals must commit to purchasing and maintaining, at their cost, an adequate supply of the medication and/or equipment used in the trial study.

### **III. PROCEDURE:**

- EMS or CQI Coordinator must notify ICEMA, in writing, expressing their interest in participating in the trial study.

- EMS or CQI Coordinator must provide rosters of all personnel documenting completion of educational offerings and/or competencies within 10 days of completion.
- EMS providers and hospitals must sign the Condition of Participation form acknowledging the terms of the trial study.